

Docket No. 371-20-055

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF APPEALS



In re Application of Helix Medical, Inc.

Filed: April 11, 2001

Technology Center: 3700

Serial No. 09/833,961

Examiner: Corrine McDermott

For: MEDICAL DEVICES HAVING ANTIMICROBIAL PROPERTIES

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patent

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

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Sir:

This is an appeal from the Final Rejection of Claims 17-22

1. *Real Party in Interest.*

The real party in interest is the Assignee of Record, Helix Medical, Inc., a California corporation.

2. *Related Appeals and Interferences.*

There are no related appeals or interferences.

3. *Status of Claims.*

Claims 1-16 stand non-elected, Claims 17-22 stand finally rejected.

Claims 17-22 stand finally rejected.

4. *Status of Amendments.*

No Amendments were filed after the Final Rejection

5. *Summary of Invention.*

The invention relates to the discovery that adding antimicrobial materials to the outside surface of the valve at an effective level, does not cause irritation of the tissue of the stoma which is only indirect fluid contact with the antimicrobial outside surface of the valve. The outside surface of the prosthesis can contain a low, non-irritating and non-toxic level of antimicrobial agents.

6. *Issues.*

Claims 17-22 are rejected under 35 U.S.C. 101 as non-statutory since the claims recite living tissue, which is a product of nature.

Claim 18 is objected to under 37 C.F.R. 1.78(c) as being non-properly dependent and to not further limit Claim 17.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laguette et al. (WO 98/08463) in view of Priscott (WO 97/1447)

7. *Grouping of the Claims.*

Claim 17 is independent.

Claim 19 limits the voice prosthesis to an elastomer.

Claim 20 relates that the valve contains a dispersion or outside coating of an antimicrobial material.

Claim 22 recites a particular amount of silver oxide, butyl paraben or triclosan dispersed in the resin forming the valve.

8. *Argument.*

Appellant request that the non-statutory objection be held in obeyance until after the Decision. Applicant will amend Claim 17 to recite that the outside surface of the body and valve are in contact with tissue when inserted into a tracheostoma of a patient. The tissue and body fluids are not present in the

claims but are defined as a future environment in the claims. Claim 18 will be cancelled and is withdrawn from the Appeal.

Laguetta discloses a tubular, silicone voice prosthesis. Prescott discloses adding triclosan to a polymer for a prosthetic device such as a voice prosthesis in a range of 0.5 to 5% by weight. However, there is no teaching nor suggestion to add an amount of triclosan effective to disrupt microbial growth only to the valve and add a lower, non-irritating amount of antimicrobial material to the surfaces of the voice prosthesis in direct contact with tissue.

9. Appendix.

17. A voice prosthesis for use in contact with tissue comprising in combination:

a tubular body having a central channel and an annular wall having an inside surface not in contact with tissue and an outside surface in contact with tissue and containing antimicrobial material at a level that is non-irritating and non-toxic to tissue;

5 a valve having an inside surface and an outside surface and being mounted to seal and intermittently open said channel, said outside surface of the valve being in contact with body fluids; and

10 the outside surface of the valve not being in direct contact with tissue and having antimicrobial properties at a level that would irritate or be toxic to that tissue.

18. A voice prosthesis according to claim 17 in which the outside surface of the wall is in contact with tissue and the outside surface of the wall is non-irritating to and non-toxic to said tissue.

19. A voice prosthesis according to claim 18 in which said body and said valve are formed of an elastomer.

20. A voice prosthesis according to claim 19 in which the valve is formed of a silicone elastomer containing a

dispersion or outside coating of an antimicrobial material.

21. A voice prosthesis according to claim 20 in which the antimicrobial material is selected from metal salts, metal oxides and organic antimicrobial materials.

22. A voice prosthesis according to claim 21 in which the material is selected from silver oxide in an amount from 6 to at least 50 phr and butyl paraben or triclosan in an amount from 0.2 to 5% by weight dispersed in the resin forming the valve.


10. *Certificate of Service.*

There are no other parties to this Appeal, except the Board of Appeals.

Conclusion

For the above reasons its is believed that the Examiner is in error as to all grounds of rejection and reversal is believed to be in order and is respectfully solicited.

Respectfully submitted,



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Sir:

Enclosed please find three (3) copies of Appellants' Brief, and check no. 5901 in the amount of \$165.00 for the fee for filing the Brief.

An oral hearing is not requested.

Please charge any additional fee in this Appeal to Deposit Account No. 10-0192. One additional copy of this Transmittal is enclosed.

Respectfully submitted,

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The Commissioner is hereby authorized to charge payment of any patent application processing fees under 37 CFR 1.17 or credit overpayment to Deposit Account No. 10-0192. A duplicate copy of this sheet is attached.

I, Marvin E. Jacobs, do hereby certify that the foregoing documents are being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date of **January 29, 2004**.

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